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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,896	08/28/2006	Toshihiro Ushijima	USHIJIMA3	5702

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,896	USHIJIMA ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 26-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 17-19* is/are rejected.

7)☒ Claim(s) *8,11-17 and 20-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/5/08 and 3/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-45 are pending in the application. Claims 1-7 and 26-45 are withdrawn. Claims 8-25 are under examination.

Election/Restrictions

Applicant's election with traverse of the invention of claims 8-25 (Group II) in Paper No. 20090318 is acknowledged. The traversal is on the ground(s) that:

> The Office Action states that unity of invention is destroyed by the Imada et al publication, whereby the four groups lack the same or corresponding special technical features as required by PCT Rules 13.1 and 13.2. Applicants respectfully submit that the Imada publication falls short of showing or even making obvious the shared special technical features which exist throughout the four groups. Please note that the Imada publication is acknowledged prior art noting page 4 of applicants' specification. Applicants further respectfully maintain that even if the Imada publication were applicable against the claims as presently pending, it would not be applicable against more narrow claims which share the same or corresponding special technical feature.

This is not found persuasive because the general inventive concept linking the inventions as grouped is a variant of *Erysipelothrix rhusiopathiae* surface protective antigen SpaA or of a shortened form thereof in which a portion of SpaA protein is deleted. This technical feature is known in the prior art as anticipated by Imada et al. Infection and Immunity, Sept. 1999, p. 4376-4382, cited in IDS and Applicants arguments set forth above state that Imada et al is acknowledged prior art. Thus, because the general inventive concept or technical feature in the

broadest claim is known in the art, the inventions lack unity irrespective of what is being claimed in the narrower claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-7 and 26-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 20090318.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

The information disclosure statement filed 3/29/07 and 9/5/08 has been considered. Initialed copies are enclosed.

Claim Objections

Claims 11, 12, 13, 14, 15, 16 and 20-25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim 8 and 17 are objected to because of the following informalities:

Please correct the grammar of "or of a shortened form thereof ΔSpaA protein in which a portion of SpaA protein is deleted". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-10 and 17-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a variant of *Erysipelothrix rhusiopathiae* surface protective antigen SpaA.

The claimed invention is drawn to a product of nature. Variants of protein naturally exist in nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of arguments and evidence of a new utility imparted by the increased purity of the claimed invention *and amendment to the claims to recite the essential purity* (e.g. isolated) of the claimed products is suggested to obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10 and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ΔSpaA protein in which amino acid substitution is introduced lacks antecedent basis because the ΔSpaA protein of claims 8 or 17 comprises a deletion not a substitution. Does Applicant mean that the ΔSpaA deletion variant *further comprises* an amino acid substitution?

Also in claim 9 and 18 how can the variant of claim 8 or 17 have the amino acid sequence of SpaA i.e. wildtype SpaA, if they are variants?

As written, it is not clear what is being claimed.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-9 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Imada et al. Journal of Clinical Microbiology, Nov. 2003, p. 5015-5021, cited in IDS.

The claims are drawn to a variant of *Erysipelothrix rhusiopathiae* surface protective antigen SpaA or of a shortened form thereof ΔSpaA protein in which a portion of SpaA protein is deleted, which is immunogenic and expressed in *E. coli* as inclusion bodies.

Imada et al teaches variants of the surface protective antigen (SpaA) of *Erysipelothrix rhusiopathiae* and compositions thereof. Said variants are shortened from of SpaA in which a portion of SpaA has been deleted. See p. 5016 column 1-2 under expression of SpaA in E.coli a

fusion protein and p. 5018 column 2 under "reactivities of the five recombinant SpaA fragments". Said variants are immunogenic absent other evidence to the contrary.

As to the limitation of being "expressed in E.coli as inclusion bodies", this is a process limitation. The instant claims are drawn to the product and not how the instant proteins are expressed or to be used later. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

As to claim 9 and 18, said variants have an amino acid sequence of SpaA i.e. the variants share amino acids in common with the wildtype SpaA i.e. the parts that are not deleted.

Claims 8-10 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Makino et al. Microbial Pathogenesis 1998; 25:101-109.

The claims are drawn to a variant of *Erysipelothrix rhusiopathiae* surface protective antigen SpaA or of a shortened form thereof ΔSpaA protein in which a portion of SpaA protein is deleted, which is immunogenic and expressed in *E. coli* as inclusion bodies.

Makino et al teaches a variant of *Erysipelothrix rhusiopathiae* surface protective antigen SpaA (Uniprot accession # 066380_ERYH) which is a shortened form i.e. a deletion variant that further comprises an amino acid substitution (see conservative substitution as compared to disclosed SEQ ID NO: 2 which is disclosed to be the amino acid sequence of SpaA, see p. 12

lines 24-25 to p. 13 lines 1-3). See sequence alignment attached to this office action (and see below) of SEQ ID NO: 2 with the SpaA of Makino et al. Makino et al teaches compositions comprising said variant, see fig. 5 p. 108 of Makino et al.

Said variants are immunogenic absent other evidence to the contrary.

As to the limitation of being "expressed in E.coli as inclusion bodies" or process of preparing said protein as in claims 10 and 19, these are process limitations. The instant claims are drawn to the product and not how the instant proteins are expressed or to be used later. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777

F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

As to claim 9-10 and 18-19, said variant has an amino acid sequence of SpaA i.e. the variants share amino acids in common with the wildtype SpaA i.e. the parts that are not deleted and the variant has an amino acid substitution.

Status of Claims

Claims 1-45 are pending in the application.

Claims 1-7 and 26-45 are withdrawn.

Claims 8, 11-17 and 20-25 are objected to.

Claims 8-10 and 17-19 are rejected. No claims allowed.

Prior Art Pertinent to Applicants Disclosure

Shimoji et al. Infection and Immunity, Apr. 1999, p. 1646-1651 (cited in IDS) teaches the regions of *Erysipelothrix rhusiopathiae* surface protective antigen SpaA.1 protein responsible for protective immunity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645